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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,777	11/06/2001	Martha A. Wild	SY01106KQ1	8204

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/993,777	Applicant(s) WILD ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-49* is/are pending in the application.

4a) Of the above claim(s) *43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-42 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 10.5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 39-49 are pending in the application. Claims 39-43, and 45-49 are under consideration.

2. Claim 43 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

3. Applicant's election of Group I in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on February 15, 2002, and January 28, 2003 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

5. The following reference is in a foreign language. However, no translation for the reference was found in the Application files. The reference has therefore been placed in to the application file, but has not been considered.

Specification

6. The disclosure is objected to because of the following informalities: On page 29 of the application, the description states that the "invention provides an isolated nucleic acid molecule encoding" one of a series of genes. However, nucleic acids do not encode genes.

On the same page (lines 5-17), the application indicates that the sequences of SEQ ID NOs: 60-70 are gene sequences. However, these sequences are actually the protein sequences encoded by the genes.

Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 39-41, and 44- 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 20, 24, and 28 of U.S. Patent No. 6,328,975. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is because the claims in the present case read on any nucleic acid comprising DNA encoding an infectious laryngotracheitis virus (ILTV) glycoprotein I (gI);

whereas the patent is claiming vectors for making recombinant virus. Claim 16 of the patent demonstrates that ILTV gI is among the foreign genes that may be inserted in to the virus through the vectors. The current claims therefore overlap with the patent claims.

9. Claims 39-41, and 44- 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 30, 33, and 35 of U.S. Patent No. 6,497,882. Although the conflicting claims are not identical, they are not patentably distinct from each other under the same rationale as indicated above with reference to patent 6,328,975.

10. Claims 39-41, and 44- 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 37, and 40-42 of U.S. Patent No. 6,221,361. Although the conflicting claims are not identical, they are not patentably distinct from each other under the same rationale as indicated above with reference to patent 6,328,975.

11. Claims 39-41, and 44-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23, 28, and 32 of U.S. Patent No. 6,033,904. Although the conflicting claims are not identical, they are not patentably distinct from each other under the same rationale as indicated above with reference to patent 6,328,975.

12. Claims 39-41, and 44-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48 and 50 of copending Application No. 09/994,064. Although the conflicting claims are not identical, they are not patentably distinct from each other because each reads on a recombinant DNA molecules comprising sequences coding for infectious laryngotracheitis virus glycoproteins I and D.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 39-42, and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims read on nucleic acids encoding for the ILTV glycoprotein I. Claims 40 and 45 limit the claimed nucleic acids to embodiments wherein the DNA is genomic DNA. The claims describe a genus of inventions of ILTV gI coding molecules, and a genus of such DNAs encompassing only nucleic acids found in viral genomes.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.
>
> Also relevant to the discussion are the following excerpts from the case of In re Borkowski and Van Venrooy, 164 USPQ 642, (CCPA 1970).

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. The claims of the present application set forth two genera of DNA molecules. First, the claims describe any DNA encoding an ILTV glycoprotein I. See e.g., claim 39. Second, the claims also claim a genus of molecules encoding a glycoprotein I wherein the DNA is genomic DNA. See e.g., claim 40. However, the applicant has provided only one example of an ILTV glycoprotein I, and one example of genomic DNA encoding the gI protein.

With regards to the claims to nucleic acids encoding any ILTV gI, the applicant has not shown that they are in possession of every ILTV gI. It is known in the art that the protein sequences of different ILTV may vary. See e.g. Johnson and Tyack, Vet. Microbiol., 46:221-231, at 225-36 (disclosing a sequence for an ILTV glycoprotein D that has a different amino acid

sequence from the sequence disclosed in the present application). See also, Leib et al. Avian diseases, Vol. 30, 835-837 (of record in the Feb. 15, 2002 IDS, indicating that ILTVs from different geographic areas have variations in restriction endonuclease patterns, thereby there are variations in the sequences of the proteins and genes of laryngotracheitis viruses). However, while the art indicates that there are variations among the proteins, the Applicant has shown possession of only one ILTV gI. One skilled in the art would not recognize from this disclosure that the Applicant was in possession of every such protein.

Claims 47 and 49 are further rejected for reading on nucleic acids that encode for not only ILTV glycoprotein I, but also for ILTV glycoprotein D. The Applicant has not provided sufficient written description for such proteins for the same reasons as is indicated with regards to ILTV glycoprotein I.

Nor has the Applicant provided sufficient written description support for the claims limited to ILTV genomic DNA coding for glycoprotein I. Aside from providing the sequence of SEQ ID NO: 1, no other information has been provided such that one skilled in the art could distinguish other ILTV genomic DNA sequences from non-genomic DNA molecules encoding the same protein. The application does not, therefore, provide adequate written description support for any genomic DNA encoding ILTV glycoprotein I other than that provided in SEQ ID NO: 1 (residues 9874-10962).

15. Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

it is most nearly connected, to make and/or use the invention. This claim reads on a nucleic acid encoding the ILTV gI protein, wherein the nucleic acid is cDNA. However, cDNA does not encode the protein encoded by the gene, as it is the complement to the coding sequence. It is suggested that the applicant amend the claim such that it is in an independent claim format (e.g., an isolated nucleic acid comprising the cDNA to the ILTV gI coding region).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 39, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al., WO 92/03554 (of record in the Feb. 15, 2002 IDS). These claims read on any isolated nucleic acid either encoding ILTV gI or comprising the cDNA thereof. The reference teaches the isolation of viral genomic DNA. Page 25. Because ILTV is a double stranded DNA virus, the isolation of the genomic DNA inherently results in isolated DNA that both encodes for the viral proteins, and cDNA. The reference therefore anticipates the identified claims.

18. Claims 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Keeler et al., U.S. Patent 5,279,965 (of record in the Feb. 15, 2002 IDS). These claims read on isolated nucleic acids encoding ILTV gI, including embodiments wherein the molecule is genomic DNA. Keeler discloses a method of isolating the genomic DNA of ILTV. Column 8, lines 19-35. Because the gI is encoded by the ILTV genome, and the reference teaches the isolation of the genomic DNA, the reference anticipates the identified claims.

19. Claims 39-41, 44, 45, 46, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochran et al., U.S. Patent 5,869,312. The rejected claims read on nucleic acid molecules, including recombinant molecules, that encode the gI protein of ILTV. In columns 20-21, the reference describes a plasmid comprising the coding region for ILTV gI, and a method of making it. The reference further discloses both the transfection of a cell with the plasmids disclosed therein to produce recombinant virus, and a method of infecting a cell with a virus comprising the DNA. Columns 13, and 31-32, respectively. The reference therefore also discloses a host cell comprising the recombinant DNA. Because the recombinant virus being made is a double stranded DNA virus, and because the plasmid containing the ILTV gI appears also to be doubles stranded, the reference would also appear to inherently teach an isolated nucleic acid comprising the cDNA of the ILTV gI gene.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
July 2, 2003

James C. Housel 7/14/03
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